Ohio Medical Corporation®

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MiniOX® 1A

Oxygen Analyzer

Operation Manual

⚠ WARNING

THIS MANUAL MUST BE READ CAREFULLY PRIOR TO THE OPERATION OF THIS DEVICE. THIS DEVICE WILL PERFORM AS DESIGNED ONLY IF USED IN ACCORDANCE WITH THE MANUFACTURER'S INSTRUCTIONS. IMPROPER USE MAY CAUSE THE DEVICE TO FAIL TO PERFORM AS DESIGNED AND MAY CAUSE INJURY TO THE PATIENT AND/OR HEALTHCARE PROFESSIONAL.

The warranties made by Ohio Medical Corporation® with respect to these products are voided if the products are not installed, used and serviced in accordance with the instructions in this manual. Please protect yourself and your patients by following them. We encourage our customers to write or call regarding this equipment prior to use or for any additional information relative to use or repairs.

This product is not intended as a life-sustaining or life-supporting device.

FEDERAL (USA) LAW RESTRICTS THIS DEVICE TO SELL BY OR ON THE ORDER OF A PHYSICIAN

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Ohio Medical Corporation®
Medical Instrument Warranty

This product is sold by Ohio Medical™ under the warranties set forth in the following paragraphs. Such warranties are extended only with respect to the purchase of this product directly from Ohio Medical or Ohio Medical's Authorized Dealers as new merchandise and are extended to the first Buyer thereof, other than for purpose of resale.

For a period of twelve (12) months from the date of original delivery to Buyer, to Buyer's order, or to an Ohio Medical Authorized Dealer, this product, other than its expendable parts, is warranted to be free from functional defects in materials and workmanship and to conform to the description of the product contained in the service manual and accompanying labels and/or inserts, provided that the same is properly operated under conditions of normal use, that regular periodic maintenance and service is performed and that replacements and repairs are made in accordance with the instructions provided. This same warranty is made for a period of sixty (60) days with respect to the expendable parts. The foregoing warranties shall not apply if the product has been repaired other than by Ohio Medical or in accordance with written instructions provided by Ohio Medical, or altered by anyone other than Ohio Medical, or if the product has been subject to abuse, misuse, negligence, or accident.

Ohio Medical's sole and exclusive obligation and Buyer's sole and exclusive remedy under the above warranties is limited to repairing or replacing, free of charge, at Ohio Medical's option, a product, which is telephonically reported to the nearest Ohio Medical Regional Service Office and which, if so advised by Ohio Medical, is thereafter returned with a statement of the observed deficiency, not later than seven (7) days after the expiration date of the applicable warranty,to the designated Ohio Medical Service Office during normal business hours, transportation charges prepaid, and which, upon Ohio Medical's examination, is found not to conform with the above warranties. Ohio Medical shall not be otherwise liable for any damages including, but not limited to incidental damages, consequential damages, or special damages.

There are no express or implied warranties which extend beyond the warranties herein above set forth. Ohio Medical makes no warranty of merchantability or fitness for a particular purpose with respect to the product or parts thereof.

General WARNINGS and CAUTIONS

⚠ WARNING

1. The MiniOX® 1A Oxygen Analyzer will perform to specifications only if it is used and serviced in accordance with the manufacturer's instructions. This instrument is to be used only by qualified, trained personnel who have carefully read the operating manual and labels and who have observed the information set forth. If this instrument does not perform as described in this manual, the instrument must not be used until the condition is rectified.
2. The MiniOX® 1A Oxygen Analyzer should be calibrated prior to each use. A two point calibration check should be performed weekly. *See Section 3, Operation*. If the instrument can not be calibrated, the sensor must be replaced. If the instrument still is unable to be calibrated, the instrument must be serviced.
3. The oxygen sensor has a minimal response to certain gases other than oxygen. Be aware of these gases and their interference levels. *See Section 5, Performance Specifications*.
4. The oxygen sensor is affected by changes in barometric pressure. *See Section 3, Effects of Pressure*, for the effects of pressure.
5. The sensor is a sealed unit containing a potassium hydroxide electrolyte. If the sensor should develop a leak, dispose of it immediately, as the sensor contains caustic material. It must be disposed of in accordance with all applicable federal, state, and local regulations. Should contact occur with skin or clothing, rinse area immediately with large quantities of water. In case of eye contact, immediately flush eyes with water for at least 15 minutes, holding eyes open. Call a physician.
6. Never operate the MiniOX® 1A Oxygen Analyzer if it is suspected that water or other liquids have entered into the case. If this occurs, immediately turn unit OFF and contact your nearest Ohio Medical Corporation Service Center for additional information.
7. Use of devices generating or emitting electromagnetic radiation near the MiniOX® 1A Oxygen Analyzer may interfere with the proper operation of the product, causing it to fail to perform as designed. Particularly, the electromagnetic radiation from the interfering device may cause the product to display incorrect/erratic values or to stop operating. Special attention should be paid to the patient if this occurs.
8. Never use the MiniOX® 1A Oxygen Monitor in combustible atmosphere, such as occurs with flammable anesthetics. Such use could result in ignition of atmosphere.
9. Never allow an excess length of cable near the patient's head or neck, as such could result in strangulation. Secure excess cable to the bed rail or other suitable object.

FAILURE TO COMPLY WITH THESE WARNINGS CAN RESULT IN SERIOUS INJURY OR DEATH OF THE PATIENT.

⚠ CAUTION

1. Remove internal battery if unit is to be non-operational for extended periods of time.
2. Observe polarity when inserting a new battery. Incorrect connection may cause damage to the instrument.
3. The MiniOX® 1A Oxygen Monitor must never be immersed in any cleaning solution, autoclaved, or exposed to temperatures greater than 70°C.
4. Use only Ohio Medical Corporation replacement parts and accessories listed in Section 3 of this manual. Analyzers can only be used with Ohio Medical Corporation sensors. Failure to do so may seriously impair the instrument's performance.

FAILURE TO COMPLY WITH THESE CAUTIONS CAN RESULT IN INSTRUMENT DAMAGE.

Definition of WARNINGS and CAUTIONS

⚠ WARNING	Statement citing a potential safety hazard and possible injury to yourself or others.
⚠ CAUTION	Statement citing a possibility of damage to the instrument or other property.
NOTE:	Advisory on instrument function.

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Section 1
Introduction

The MiniOX® 1A Oxygen Analyzer is designed to provide spot checking of oxygen concentrations from pressure swing absorptive devices (e.g. oxygen concentrators).

⚠ WARNING

This instrument is not equipped with an audible or visual alarm, and therefore must not be used in a life-support system.

The MiniOX® 1A Oxygen Analyzer (Figure 1-1):

- Operates by a single push of a switch.
- Calibrates with the turn of a dial.
- Features an easy-to-read digital display.

The galvanic oxygen sensor measures oxygen concentrations from 0 to 100%. The sensor is maintenance-free and will operate for one year, in normal medical use.

Figure 1-1
MiniOX® 1A Oxygen Analyzer

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Section 2
Principle of Operation

Each MiniOX® 1A Oxygen Analyzer uses a galvanic oxygen sensor which is long-lived and maintenance-free.

The sensor consists of two electrodes:

- a cathode
- an anode

The gold cathode is exposed to the atmosphere through a fluoropolymer membrane. The lead anode is submersed in a potassium hydroxide solution.

When oxygen diffuses through the membrane, the electrochemical reduction of oxygen on the cathode and the corresponding oxidation of the anode generate an electrical current. The current produced is proportional to the partial pressure of oxygen in the sample atmosphere. The resulting electrical current is monitored, temperature compensated, and amplified to drive the display.

The sensor is self-zeroing; when no oxygen is present to be chemically reduced, minimal current is produced. Thus, approximately zero percent oxygen is displayed.

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Section 3
Operation

Set-up Procedures

1. Remove the contents from the shipping carton and verify that you have one each of the following items:
   - MiniOX® 1A Oxygen Analyzer
   - 9-Volt Alkaline Battery
   - Oxygen Sensor in its container
   - MiniOX® 1A Operation Manual/Service Guide CD
   - Tubing
   - Male Universal Nipple Adapter
2. Remove the four screws holding the back panel in place.
3. Install the battery.
4. Remove the sensor from its container.
5. Place green washer over threads of sensor then screw the sensor into the flow block and hand-tighten. Do not overtighten or cross thread.
6. Plug the sensor connector into the printed circuit board connector mate labelled **J1**.
7. Replace the back panel and screws.
8. After installing the sensor, allow to equilibrate prior to calibration.
9. Proceed to Calibration procedures.

Calibration

The most accurate method to calibrate the MiniOX® 1A Oxygen Analyzer is with 100% oxygen. Calibrating with room air is less desirable but still acceptable, assuming the concentration of oxygen in room air is 20.8%.

1. Press the ON/OFF switch on the side panel to turn on the instrument.
2. Place the sensor in a flow of air with a known oxygen concentration or in room air.
3. Wait for at least one minute, or until the reading has stabilized.
4. If the reading on the display is other than the known or assumed oxygen concentration, adjust the reading using the calibration dial. Turn clockwise to increase the reading, or counter clockwise to decrease the reading.
5. If the reading cannot be adjusted to the known concentration value, the sensor or instrument is malfunctioning and must be serviced.

NOTE: To ensure accurate operation, the instrument should be calibrated at the flow rate of intended use.

Two-point Calibration Check

The purpose of a two-point check is to determine the linearity of the sensor. Serious deviation from linearity (±2%) indicates the sensor is nearing end-of-life. To perform a two-point linearity check:

1. Place the sensor in a stream of a known oxygen concentration between 90-100% until the reading stabilizes.
2. Calibrate to match this concentration.
3. After calibration, measure room air; the reading should be 20.8% ±2%. (A ±2% linearity variation is allowed for differences due to the method of sample introduction, the accuracy of gas concentration, and the precision of initial setting.) If the variation is greater than 2%, repeat the two-point linearity check. If the variation remains greater than 2%, replace the sensor.

Instrument Operation

The MiniOX® 1A Oxygen Analyzer has a low battery indicator. When the Low Battery indicator is activated, LO BAT appears on the top left of the display. The instrument functions normally for approximately eight hours; however, replace the battery as soon as possible.

If the battery is not replaced, the instrument's display will go blank. If the sensor becomes disconnected while the instrument is in use, the instrument displays between -0.2 and +0.2.

The instrument is designed to read in percent from 0 to 100%; however, if incorrectly calibrated, it displays up to 199.

To maximize battery life, turn OFF the MiniOX® 1A Oxygen Analyzer when not in use.

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Instructions for Use

Installation (FIGURE 3-1)

1. If so equipped, remove the humidifier from the oxygen concentrator.
2. If the concentrator is equipped with a male DISS fitting, thread the female DISS fitting of the MiniOX® 1A Oxygen Analyzer onto it and proceed to Step 5.
3. If the concentrator is equipped with a nipple adapter, thread the provided male universal nipple adapter into the female DISS fitting of the MiniOX® 1A Oxygen Analyzer and proceed to Step 4.
4. Connect the nipple adapter on the MiniOX® 1A Oxygern Analyzer to the nipple adapter on the concentrator using the oxygen tubing provided.
5. Analyze the oxygen concentration, ensuring that the flow rate does not exceed four liters-per-minute.
6. When the oxygen analysis is complete, remove the sampling apparatus and reinstall the humidifier, if so configured.

Sensor Operation

The oxygen sensor has a minimal response to certain gases other than oxygen. Be aware of these gases and their interference levels. *See Section 5, Interferent Gases and Vapors*.

The sensor is a sealed unit containing a potassium hydroxide electrolyte.

⚠ WARNING

If the sensor develops a leak, dispose of it immediately as sensor contains caustic material; it must be disposed of in accordance with all applicable federal, state and local regulations. Should contact occur with skin or clothing, rinse area with large quantities of water. In case of eye contact, immediately flush eyes with water for at least 15 minutes, holding eyes open. Call a physician.

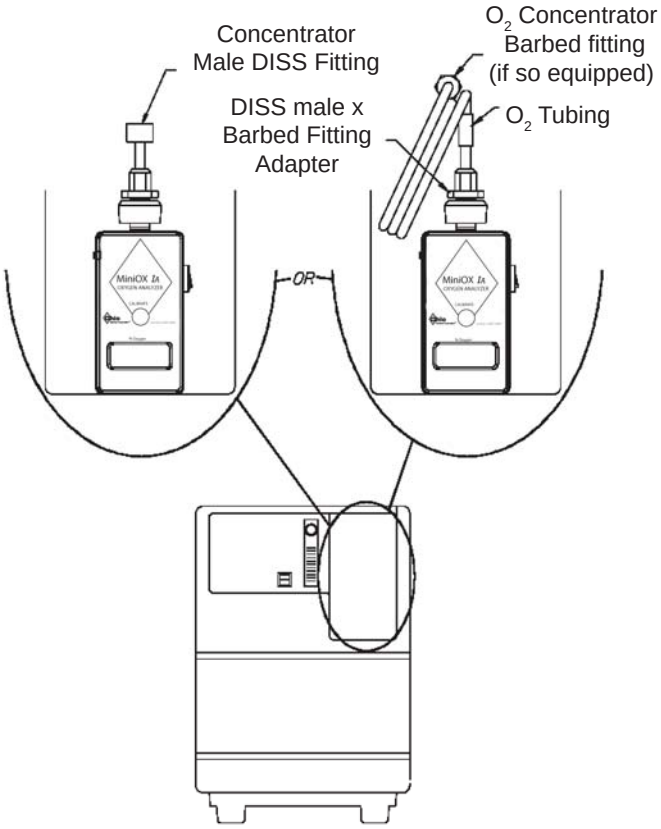

Figure 3-1
MiniOX® 1A Installation

Effects of Pressure, Humidity and Temperature

⚠ CAUTION

To ensure accurate and reliable oxygen analysis, a thorough understanding of the effects of pressure, humidity, and temperature on the sensor is necessary.

Effects of Pressure

The sensor actually senses partial pressure of oxygen, not percentage. Changes in barometric pressure change the reading, even if the percent of oxygen in the sample remains constant.

Partial pressure of oxygen (PO_2) equals the percent of oxygen(% O_2) times (x) the pressure at which the sample is measured (mmHg-mercury):

$$PO_2 = (\%O_2)\ (mmHg)$$

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For example:

At sea level the pressure equals 760 mmHg and dry air contains 21% O_2. Therefore;

$$PO_2 = (21\%)\ (760\ mmHg)$$
$$PO_2 = 160\ mmHg$$

If the instrument is calibrated to read 21% at 160 mmHg partial pressure, and the instrument is then moved to an area above sea level where the atmospheric pressure is 700 mmHg, a lower reading is found due to a lower partial pressure.

$$PO_2 = (21\%)\ (700\ mmHg)$$
$$PO_2 = 147\ mmHg$$

The percent reading on the instrument is derived by the following formula:

$$X = \frac{(21\%)\ (147\ mmHg)}{(160\ mmHg)} = 19.3\%$$

Therefore, to eliminate error caused by pressure changes, the instrument must be calibrated at the pressure and flow rate at which it is to be used.

⚠ CAUTION

Do not expose the sensor to pressure outside the range of 600 to 900 mmHg, (23.62 to 35.43 inches Hg.) as this can produce instrument errors.

Effects of Humidity

The presence of humidity in an oxygen sample decreases the actual concentration of oxygen. Humidity in a sample has the same effects as diluting the sample with another gas.

For example:

If 100% oxygen is saturated with 100% humidity, the actual concentration of oxygen drops from 100% to 96-97%. The instrument indicates this drop in concentration.

Effects of Temperature

Each MiniOX® 1A sensor is desensitized to temperature changes using a thermistor (temperature variable resistor) located within the sensor. Variations in the sensor reading due to temperature changes, are less than 3% when used or calibrated between 0 to 40 degrees centigrade. By using the instrument close to the temperature at which it is calibrated, variations can be minimized.

Operating Temperature Range:
0º to 40ºC (32º to 104ºF)

⚠ CAUTION

Do not use instrument outside operating temperature range.

⚠ CAUTION

Do not handle the sensor more than necessary during calibration or use. Body heat can cause the sensor's thermistor to change disproportional to the change in gas sample temperature at the sensing electrode. This can produce some error, until thermal equilibrium is restored.

Section 4
Maintenance and Care

Battery Replacement

The MiniOX® 1A Oxygen Analyzer requires one 9-volt alkaline battery. To replace the battery:

1. Verify the instrument is turned OFF. If it is ON, press the ON/OFF switch on the side panel to turn the instrument OFF.
2. Remove the back panel, which is held in place by four small screws.
3. Remove and safely or properly discard the old battery; replace with a new battery.
4. Replace the back panel and reinstall the screws.
5. Wait 10 seconds after connecting the new battery before turning the instrument ON.
6. Recalibrate the instrument. *See Section 3, Calibration*.

Sensor Replacement

⚠ WARNING

Under no circumstances should any adjustments other than those outlined in this procedure be made to other controls in the instrument. Any alteration of other controls may affect the operation and accuracy of the instrument and will void the warranty.

When the MiniOX® 1A Oxygen Analyzer is unable to be calibrated, or gives erratic readings, the sensor must be replaced. To replace the sensor:

1. Verify the instrument is turned OFF. If it is ON, press the ON/OFF switch on the side panel to turn the instrument OFF.
2. Remove the old sensor by un-threading the sensor from the flow block.
3. Thread the new sensor into the flow block and hand-tighten.

⚠ CAUTION

Do not overtighten or cross thread.

4. Recalibrate the instrument. *See Section 3, Calibration.*

Cleaning, Disinfection and Sterilization

⚠ CAUTION

Never autoclave, immerse, or expose the MiniOX® 1A Oxygen Analyzer (including sensor) to high temperatures (>70°C). Never expose the device to pressure, irradiation, vacuum, steam, or chemicals (other than alcohol or mild cleaning agents).

Clean the instrument and sensor by wiping with a cloth lightly dampened with Isopropyl Alcohol or mild detergent. Make sure that no moisture seeps into the instrument case.

Instrument

When cleaning or disinfecting the instrument, care must be taken to prevent entry of solutions into the instrument case.

Cleaning

The external surfaces of the unit may be cleaned by wiping them with a cloth moistened with a mild detergent solution.

Disinfection

The external surfaces of the unit may be disinfected by wiping them with a cloth moistened with ethanol or Cidex. The instrument is not designed to withstand the conditions imposed by steam, ethylene oxide or radiation sterilization.

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Section 5
Specifications

Performance Specifications			
Range	0-100% O_2		
Display Resolution	0.1% O_2 increments		
Linearity	±2% of full scale		
Accuracy	±2% of full scale		
Low Battery Indicator	"LO BAT" appears on the display		
Warm-Up Time	None required		
Operating Temperature Range	0° to 40°C (32° to 104°F)		
Storage Temperature Range	-20° to 55°C (-4° to 131°F)		
Humidity	0 to 95% RH (non condensing)		
Power Requirements	One 9-volt alkaline battery		
Battery Life	Approximately 1,400 hours		
Instrument Dimensions	5-11/16" x 2-1/2" x 1-3/4"		
Instrument Weight	11 oz.		
Sensor Type	Galvanic fuel sensor 0-100% O_2		
Sensor Life	One year in normal medical conditions.		
Sensor Shelf Life	Sensors, as shipped, can be stored for a maximum of 6 months without degradation of life		
Response Time Measured @ 25°C	**FLOW RATE LITERS/ MIN.**	**90% OF CHANGE (SECONDS)**	**97% OF CHANGE (SECONDS)**
	2	14	22
	4	13	21
	6	12	20

Interferent Gases and Vapors		
INTERFERENT	**% BY VOLUME (DRY GAS)**	**INTERFERENT EQUIVALENT OF PERCENT O_2**
Carbon Dioxide	12%	<0.1%
Cyclopropane	50%	<0.1%
Diethyl Ether	20%	<1.5%
Enflurane	4%	<0.5%
Halothane	5%	<0.9%
Helium	80%	<0.2%
Methoxyflurane	4%	<2.3%
Nitrogen	80%	<0.2%
Nitrous Oxide	80%	<0.8%

Instrument Replacement Parts	
ITEM	**PART NUMBER**
Case Screw	637408
4-x3/8" stainless steel screws (set of 4)	450000

Accessories	
ITEM	**PART NUMBER**
Alkaline Battery, 9-Volt	628817
Operating Manual CD	600700
Operating Manual, printed	806129
Oxygen Sensor	806572
MiniOX® 1A Oxygen Analyzer	804174
Oxygen Tubing	637258
Male Universal Nipple Adapter	638064
Carrying Case	710462

Servicing	
Inspection and Servicing	SVC-1A1
Cleaning, Calibration and Testing	SVC-1A2
Enclosure Replacement	SVC-1A3
Circuit Board Replacement	SVC-1A4
Connector Replacement	SVC-1A5

NOTES:

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